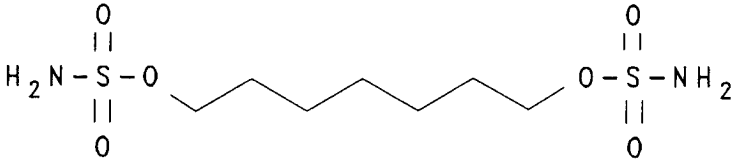
HEPSULFAM WITH DILUENT

NSC - 329680



Chemical Name: Sulfamic Acid, 1,7-Heptanediyl ester

CAS Registry Number: 96892-57-8

Molecular Formula: $C_7H_{18}N_2O_6S_2$ **M.W.**: 290.4

How Supplied: Hepsulfam is available in a duopack containing the lyophilized drug and a sterile special diluent that must be aseptically combined prior to use, forming the "combined solution".

Each duopack contains:

NSC - 329680: One 10 mL flint vial containing 150 mg of hepsulfam.

NSC - 652019: One 5 mL flint ampule containing 5 mL of special diluent composed of ethanol 10% (v/v) and propylene glycol 40% (v/v) in pH 7.4, 0.05 M phosphate buffer.

Solution Preparation: Aseptically add 4.8 mL of the special diluent to the vial containing 150 mg of hepsulfam. The resulting solution will contain hepsulfam 30 mg/mL in ethanol 10% (v/v), propylene glycol 40% (v/v), and pH 7.4 , 0.05 M phosphate buffer. Use no other diluent for initial constitution.

Storage: Store the intact packages under refrigeration (2-8 °C).

Stability: The intact vials and diluent ampules bear a preparation date. Shelf-life evaluation is ongoing.

The "combined solution" is physically and chemically stable for at least 72 hours at room temperature (22-25 °C).

The "combined solution" may be further diluted with 5% Dextrose Injection, USP or 0.9% Sodium Chloride to a concentration of 3 mg/mL. The solution is physically and chemically stable for at least 24 hours at room temperature (22-25 °C).

> **CAUTION**: The single-use vacuum dried dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous